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NOTICE OF ALLOWANCE AND FEE(S) DUE

20995

7590

02/24/2010

KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE. CA 92614

EXAMINER				
LEE, JAE W				
ART UNIT	PAPER NUMBER			
1656				

DATE MAILED: 02/24/2010

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517.225	06/09/2005	Dario Alessi	ERP01.005APC	2433

TITLE OF INVENTION: METHODS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	05/24/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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(571)-273-2885 or <u>Fax</u>

maintenance fee notifications.

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 20995 7590 02/24/2010 Certificate of Mailing or Transmission KNOBBE MARTENS OLSON & BEAR LLP I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 2040 MAIN STREET FOURTEENTH FLOOR **IRVINE, CA 92614** (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/517,225 06/09/2005 Dario Alessi ERP01.005APC 2433 TITLE OF INVENTION: METHODS APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 05/24/2010 **EXAMINER** ART UNIT CLASS-SUBCLASS LEE, JAE W 1656 703-011000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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2040 MAIN STRE			ART UNIT	PAPER NUMBER
FOURTEENTH FLOOR IRVINE, CA 92614			1656 DATE MAILED: 02/24/201	0

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 974 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 974 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)	
	10/517,225	ALESSI ET AL.	
Notice of Allowability	Examiner	Art Unit	
	 JAE W. LEE	1656	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIP of the Office or upon petition by the applicant. See 37 CFR 1.313 1. This communication is responsive to 01/18/2010.	(OR REMAINS) CLOSED or other appropriate comm IGHTS. This application is	in this application. If not included nunication will be mailed in due cours	
2. X The allowed claim(s) is/are <u>1-8,11-13,16,43 and 44.</u>			
 3. Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). 	been received. been received in Applicat	ion No	rom the
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be subminformal patent APPLICATION (PTO-152) which give	IENT of this application. itted. Note the attached EX	(AMINER'S AMENDMENT or NOTIC	
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") mus (a) ☐ including changes required by the Notice of Draftspers 	st be submitted.		
1) hereto or 2) to Paper No./Mail Date	•	,	
(b) including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in the state of the sheet.	.84(c)) should be written on	the drawings in the front (not the back) of
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT	sit of BIOLOGICAL MA	ΓERIAL must be submitted. Note t	he
Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ☐ Interview Paper No 7. ☑ Examiner'	nformal Patent Application Summary (PTO-413), ./Mail Date s Amendment/Comment s Statement of Reasons for Allowand	ce

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Daniel Altman on 02/10/2010. Claims 1-8, 11-13, 16, 43 and 44 are allowed.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Please replace the title "Methods" with "Methods for selecting a candidate compound using a three-dimensional structure of phosphoinositide dependent protein kinase 1 (PDK1)".

Please amend the claims as they appear below:

A clean copy of Claim 1 is provided as shown below:

Claim 1. A method for selecting a compound for modulating the activity of phosphoinositide dependent protein kinase 1 (PDK1), the method comprising:

Art Unit: 1656

[i] generating a three-dimensional structure of the protein kinase catalytic domain of PDK1 as defined by Example 2, 3, 7 or 8;

[ii] identifying predicted binding region(s): the PDK1 Interacting Fragment (PIF) binding pocket formed by residues including residues Lys115, Ile118, Ile119 on the α B helix, Val124, Val127 on the α C helix, and Leu 155 on β -sheet 5 of full length human PDK1 as set forth in SEQ ID NO: 3, the "phosphate binding pocket" formed by residues including residues Lys76, Arg131, Thr148 and Gln150 of full length human PDK1 as set forth in SEQ ID NO: 3, and/or the α C helix formed by residues 123-136 of full length human PDK1 as set forth in SEQ ID NO: 3 in any of the models generated in step [i];

[iii] modeling a plurality of three-dimensional structures of candidate compounds;

[iv] comparing said three-dimensional structure of the protein kinase catalytic domain of PDK1 binding regions/pockets as identified in step [ii] with the three-dimensional structure of each of said candidate compounds of step [iii]; and

[v] selecting one of the candidate compounds as a compound for modulating the activity of phosphoinositide dependent protein kinase 1 (PDK1).

Art Unit: 1656

Claim 2. Replace "(SEQ ID NO. 3) or a fusion thereof" with "as set forth in SEQ ID NO: 3".

Claim 3. Replace "claim 2" in line 1 with "claim 1"; and replace "(SEQ ID NO. 3)" with "as set forth in SEQ ID NO: 3".

Claim 4. Replace "(SEQ ID NO. 3) or a fusion thereof" with "as set forth in SEQ ID NO: 3".

Claims 9 and 10. Canceled.

Claim 12. Replace "(SEQ ID NO: 2)" with "as set forth in SEQ ID NO: 2".

A clean copy of Claim 13 is provided as shown below:

Claim 13. A method for selecting a compound for modulating the activity of PDK1 Interacting Fragment (PIF) binding pocket containing protein kinase, the method comprising:

[i] modeling a three-dimensional structure of a plurality of molecules in a computer;

Art Unit: 1656

[ii] generating a three-dimensional structure of the protein kinase catalytic domain of PDK1 as defined by Example 2, 3, 7 or 8;

[iii] comparing the three-dimensional structure of each of said molecules with the three-dimensional structure of said phosphate binding pocket of human PDK1 and optionally also said hydrophobic pocket of human PDK1;

[iv] identifying a molecule from the plurality of the modeled molecules which binds to said PIF binding pocket in the position equivalent to a hydrophobic pocket of human PDK1 that is defined by residues including Lys115, Ile118, Ile119, Val124, Val127 and Leu155 of full-length human PDK1 as set forth in SEQ ID NO: 3, and/or a phosphate binding pocket in the position equivalent to the phosphate binding pocket of human PDK1 that is defined by residues including Lys76, Arg131, Thr148 and Gln150 of SEQ ID NO: 3; and

[v] selecting one of the modeled molecules as said compound based on a predicted ability of the molecule to interact with said phosphate binding pocket of protein kinase or said hydrophobic pocket of protein kinase,

wherein the three-dimensional structure or a part thereof is determined for a polypeptide comprising residues 51 to 359 of full length human PDK1 as set forth in SEQ ID NO: 3.

Claims 14 and 15. Canceled.

Claims 43 and 44. Replace "prior" with "prior to".

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached between 9:00 to 5:30 on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

Art Unit: 1656

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/ Examiner, Art Unit 1656

/SUZANNE M. NOAKES/ Primary Examiner, Art Unit 1656